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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/874,400 | 06/04/2001 | Werner G. Kuhr | 407T-894701US | 5307 |

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,400

Applicant(s)

KUHR ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

1. This action is in response to papers filed 7 April 2003 in which claims 1, 7 and 8 were amended. All of the amendments have been thoroughly reviewed and entered. The previous objections of the specification and Claims 7 and 8 are withdrawn view of the amendments. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are maintained. The previous rejections under the judicially created obviousness-type double patenting are withdrawn in view of Applicant's arguments. All of the arguments have been thoroughly reviewed. The arguments regarding the maintained rejections are discussed below.

Claims 1-21 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1, 3-8 and 10-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (U.S. Patent No. 6,168,948 B1, filed 12 January 1998).

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Regarding Claim 1, Anderson et al disclose a method of detecting two or more analytes in a sample comprising: providing a channel having affixed therein a binding partner for each of said two or more analytes wherein the binding partner for each of said analytes are located in different regions of the channel wherein the channel has a cross-sectional area small enough such that when analytes are released from said binding partners (Column 41, lines 31-58) wherein said analytes remain spatially segregated until they reach a detection point in the channel downstream from the binding partners i.e. the method further utilizes capillary electrophoresis to analyze the analytes (Column 15, lines 10-12 and 26-32).

Regarding Claim 3, Anderson et al disclose the method wherein the channel is a capillary tube (Column 15, lines 26-32).

Regarding Claim 4, Anderson et al disclose the method wherein the capillary tube is a capillary electrophoresis tube (Column 15, lines 26-32).

Regarding Claim 5, Anderson et al disclose the method wherein the channel is a channel etched in a surface (Column 18, lines 54-58).

Regarding Claim 6, Anderson et al disclose the method wherein the channel is etched in a glass surface (Column 18, lines 54-58).

Regarding Claim 7, Anderson et al disclose the method wherein the channel is a channel in a ceramic (Column 16, lines 8-10 and Column 20, lines 27-44).

Regarding Claim 8, Anderson et al disclose the method wherein the channel is a channel in a plastic (Column 19, lines 56-61).

Regarding Claim 10, Anderson et al disclose the method wherein the channel has a cross-sectional diameter of less than about 100 μ m (Column 30-34).

Regarding Claim 11, Anderson et al disclose the method wherein the channel has a cross-sectional width of less than about 500 μ m (Column 30-34).

Regarding Claim 12, Anderson et al disclose the method wherein the channel has a cross-sectional width of less than about 100 μ m (Column 30-34).

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Regarding Claim 13, Anderson et al disclose the method wherein the two or more analytes comprise at least three different analytes i.e. total mRNA (Column 41, lines 22-30).

Regarding Claim 14, Anderson et al disclose the method wherein the binding partners are nucleic acids i.e. poly-t oligos (Column 41, lines 22-30).

Regarding Claim 15, Anderson et al disclose the method wherein the binding partners are nucleic acids i.e. poly-t oligos (Column 41, lines 22-30).

Regarding Claim 16, Anderson et al disclose the method wherein passing the fluid comprises fluid flow induced by a pressure difference Column 26, lines 1-7).

Regarding Claim 17, Anderson et al disclose the method wherein passing the fluid comprises electroosmotic fluid flow (Column 40, lines 47-54).

Regarding Claim 18, Anderson et al disclose the method wherein the sample comprises fluid selected from blood, plasma and oral fluid (Column 39, lines 10-12).

Response to Arguments

4. Applicant argues that Anderson et al does not anticipate the instant invention because they do not teach different binding partners located in different regions of the channel and further do not teach spatial segregation of different analytes as described and illustrated in the specification. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "different binding partners" "different analytes" and "spatial segregation of different analytes") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims as amended recite "two or more binding partners each specific for one of two or more analytes. The claims do not recite "different" analytes or "different" binding partners. As written, the claims encompass a plurality (i.e. two or more) of the same analytes and binding partners. Therefore, the claims

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encompass the method of Anderson, which comprises tethered poly-T oligos (a plurality of binding partners) and expressed mRNAs (a plurality of analytes) (Column 41, lines 22-30).

However, even if the claims were amended to recite "different binding partners" and "different analytes" the claims would be obvious over the teaching of Anderson et al comprising expressed mRNAs in view of the teaching of Oku et al (U.S. Patent No. 6,448,001). Oku et al teach immobilizing of different binding partners for detecting two or more analytes (Abstract). It is noted that Oku et al is not cited as new grounds for rejection because the claims are not drawn to different analytes and different binding partners.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, filed 12 January 1998).

Regarding Claim 2, Anderson et al teach a method of detecting two or more analytes in a sample comprising: providing a channel having affixed therein a binding partner for each of said two or more analytes wherein the binding partner for each of said analytes are located in different regions of the channel wherein the channel has a cross-sectional area small enough such that when analytes are released from said binding partners (Column 41, lines 31-58) wherein said analytes remain spatially segregated until they reach a detection point in the

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channel downstream from the binding partners i.e. the method further utilizes capillary electrophoresis to analyze the analytes (Column 15, lines 10-12 and 26-32) and they teach the analytes are "generally be labeled" (Column 11, lines 20-21) which suggests the analytes are sometimes not labeled. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use unlabeled analytes in the method of Anderson et al based on their suggestion and based on available detection apparatus for the obvious benefits of convenience and economy of time and labor by eliminating the labeling step and using available detection apparatus.

Regarding Claims 19 and 20, Anderson et al teach the method wherein the label is selected from radiolabel, biotin label, fluorophore label, gold particle label or any other detectable label (Column 1, lines 32-49) and they teach electronic detection (Column 15, lines 10-12) but they do not specifically teach the detection comprises absorbance spectroscopy and voltammetry. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to detect the spectroscopy and voltammetry detectable labels taught by Anderson et al and based on available spectroscopy and voltammetry detection apparatus and to detect the analytes using absorbance spectroscopy and voltammetry for the obvious benefits of convenience of using available detection apparatus.

Regarding Claim 21, Anderson et al teach the method wherein the analyte is amplified prior to detection thereby increasing the concentration of analyte (Column 8, line 61-Column 9, lines 14) but they do not teach detection of analytes at a concentration of less than 10^{-9} M. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Anderson et al using routine experimentation to amplify the analytes whereby analytes having an original concentration of less than 10^{-9} M are detected for the obvious benefits of detecting rare analytes and thereby accurately analyzing the sample for the presence of analytes.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, filed 12 January 1998) in view of Yager (U.S. Patent No. 6,007,775, issued 28 December 1999).

Regarding Claim 2, Anderson et al teach a method of detecting two or more analytes in a sample comprising: providing a channel having affixed therein a binding partner for each of said two or more analytes wherein the binding partner for each of said analytes are located in different regions of the channel wherein the channel has a cross-sectional area small enough such that when analytes are released from said binding partners (Column 41, lines 31-58) wherein said analytes remain spatially segregated until they reach a detection point in the channel downstream from the binding partners i.e. the method further utilizes capillary electrophoresis to analyze the analytes (Column 15, lines 10-12 and 26-32) but Anderson et al are silent regarding a cross-sectional area that provides a Reynold's number of less than about 1. However, it was well known in the art at the time the claimed invention was made that channels having a Reynold's number of less than about 1 were desirable because a low Reynold's number provides laminar flow (see Yager, Column 4, line 59-Column 5, line 5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cross-sectional area of Anderson's channels to provide a Reynold's number of less than about 1 for the obvious benefits of laminar flow i.e. facilitates analyte diffusion and detection as taught by Yager (Column 4, line 59-Column 5, line 14).

Response to Arguments

8. Applicant reiterates the arguments presented above regarding Anderson et al not teaching different binding agents and different analytes. The arguments have been considered and discussed above.

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9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 23, 2003